



Atty. Docket No. 01261/2/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

THE APPLICATION OF:

GAO, et al.

SERIAL NUMBER: 10/632,737

FILED: JULY 31, 2003

TITLE: PHARMACEUTICAL DOSAGE
FORM COMPRISING A
SULFITE COMPOUND

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) EXAMINER: Unknown
)
) GROUP ART UNIT: Unknown
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INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97(b)

Commissioner for Patents
P.O. BOX 1450
Alexandria VA 20231-1450

Dear Sir:

This Information Disclosure Statement (IDS) is filed in accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§ 1.97-1.98, as supplemented by MPEP § 609. Presentation of documents listed on enclosed Form PTO-1449 is not an admission that any listed document is prior art under 35 U.S.C. No patents or publications reviewed or considered by the inventors or undersigned attorney is believed to constitute a *prima facie* case of unpatentability.

This IDS is filed under the provisions of § 1.97(b), as it is believed submitted prior to the mailing of a first Office Action on the merits. Accordingly, no fee is believed payable in respect of this IDS. However, if it is determined that a fee is payable, please charge such fee to Deposit Account No 19-1025.

Respectfully submitted,

Kenton N. Fedde, Reg. No. 54,701
Attorney for Applicant
Telephone: (314) 274-5402



Sheet 1 of 2

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| FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | ATTY. DOCKET NO.: 01261/2/US | APPLICATION NO.: 10/632,737 |
| | INVENTOR: GAO, et al. | |
| | Filed: JULY 31, 2003 | Group: |

U.S. PATENT DOCUMENTS

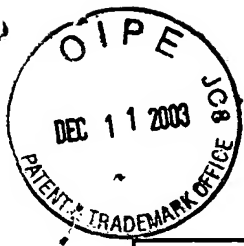
| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|---------------------|-----|--------------------|-------------------|--------------------------|-------|----------|-------------------------------|
| | A1 | 3,592,945 | 13 July 1971 | Pesch. | 252 | 316 | 07 March 1968 |
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| | A8 | 4,720,924 | 26 January 1988 | Hradecky <i>et al.</i> | 34 | 1 | 03 November 1986 |
| | A9 | 4,744,988 | 17 May 1988 | Brox. | 424 | 456 | 17 December 1986 |
| | A10 | 4,756,902 | 12 July 1988 | Harvey <i>et al.</i> | 424 | 454 | 25 July 1986 |
| | A11 | 4,804,542 | 14 February 1989 | Fischer <i>et al.</i> | 424 | 456 | 09 April 1987 |
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| | A14 | 5,146,758 | 15 September 1992 | Herman. | 62 | 62 | 04 March 1991 |
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| | A18 | 6,350,468 | 26 February 2002 | Sanso. | 424 | 456 | 14 December 1998 |

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| | | Document Number | Date | Country | Class | Subclass | Yes | No |
| | B1 | WO 84/00919 | 15 March 1984 | PCT | | | | |
| | B2 | WO 85/04100 | 26 September 1985 | PCT | | | | |
| | B3 | WO 92/15828 | 17 September 1992 | PCT | | | | |

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| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

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| | INVENTOR: GAO, et al. | |
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| Examiner Initial | | |
|---------------------|----|--|
| | C1 | <u>Industrial Solvents Handbook</u> ; 5th ed., p 392, Noyes Data Corporation, Westwood, NJ; Flick (1998) |
| | C2 | <u>Pharmaceutical Dosage Forms and Drug Delivery Systems</u> ; 6th ed., pp 176-182, Williams & Wilkins, Baltimore, MD Ansel <i>et al.</i> (1995) |
| | C3 | <u>Remington: The Science and Practice of Pharmacy</u> ; 19th Ed., pp 1646-1647, Mack Publishing Co. Easton. PA |
| | C4 | <u>United States Pharmacopoeia</u> ; 24th ed., pp 2254-2298; 2299-2304, (USP 24), 2000 |
| | C5 | Collaborative Development of Two-Tier Dissolution Testing for Gelatin Capsules and Gelatin-Coated Tablets using Enzyme-Containing Media, Stimuli to the Revision Process; Pharmacopeial Forum, Vol. 25, No. 5, pp 7045-7050, Sept.-Oct. 1998 |
| | C6 | Singh <i>et al.</i> , <u>Alteration in Dissolution Characteristics of Gelatin Containing Formulations</u> ; <i>Pharmaceutical Technology</i> , 26 (4) 36-58, April 2002 |

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|---|------------------------|
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